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PATENT COOPERATION TREATY

PCT

PCT/JP2003/013254



Translation

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PS0304	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/013254	International filing date (day/month/year) 16 October 2003 (16.10.2003)	Priority date (day/month/year) 16 October 2002 (16.10.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/00, 15/09, 1/00, C12M 1/00 // A61K 48/00, A61P 35/00		
Applicant UNIVERSAL BIO RESEARCH CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 7 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☒ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 13 May 2004 (13.05.2004)	Date of completion of this report 12 January 2005 (12.01.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ The international application as originally filed/furnished
- ☒ the description:
- pages _____ 1-4, 6-41 _____, as originally filed/furnished
- pages* _____ 5 _____ received by this Authority on _____ 01 November 2004 (01.11.2004)
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____ 2-18, 20-27, 29, 30, 32-36, 38-41 _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ 1, 19, 28, 31, 37 _____ received by this Authority on _____ 01 November 2004 (01.11.2004)
- pages* _____ received by this Authority on _____
- ☒ the drawings:
- pages _____ 1-15 _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
See supplemental sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _____.

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The subject matter common to independent claims 1, 19, 27, 31 and 37 (invention group A) and independent claim 28 (invention group B) relates to a magnetic carrier.

However, the magnetic carrier is disclosed in JP 6-133784 A (Research Development Corporation of Japan), 17 May 1994 and hence, lacks novelty. There appears to be no other common subject matter that can be considered as a special technical feature.

Such being the case, it appears that there is no technical relationship between these two groups of inventions involving one of more of the same or corresponding special technical features and these two groups are not considered as being so linked as to form a single general inventive concept.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-27, 31-41	YES
	Claims	28-30	NO
Inventive step (IS)	Claims	1-26, 31-41	YES
	Claims	27-30	NO
Industrial applicability (IA)	Claims	1-41	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 7-241192 A (TDK Corp.), 19 September 1995

Document 2: JP 6-133784 A (Research Development Corporation of Japan), 17 May 1994

Document 3: F. Toneguzzo, et al., "Electric field-mediated gene transfer: characterization of DNA transfer and patterns of integration in lymphoid cells." Nucleic Acid Research, 1988, Vol. 16, No. 12, pages 5515-5532

Document 4: WO 94/09145 A1 (Cangene Corporation), 28 April 1994

Document 5: EP 866123 A1 (Eppendorf-Netheler-Hinz GmbH), 23 September 1998

Claims 1-26 and 31-41

The inventions set forth in claims 1-26 and 31-41 are novel and involve an inventive step in relation to documents 1-5 cited in the international search report.

Document 1 discloses an apparatus for introducing biological material having a specific structure and a method for introducing biological material for introducing desired genes into target cells through the application of a magnetic field. Document 2 discloses specific magnetic particles for the introduction of biological material and a cell separation process using said magnetic particles.

Documents 3-5 disclose a process for perforating cells.

However, none of the above-listed documents discloses or suggests an apparatus for introducing biological material and a method for introducing biological material for introducing desired DNA into target cells through the application of a magnetic field, wherein magnetic fields are applied from at least two directions to the container unit with said container unit situated between the fields. Moreover, this feature would not be obvious to a person skilled in the art.

Claim 27

The invention set forth in claim 27 does not involve an inventive step in the light of documents 1 and 2 cited in the international search report.

The invention set forth in independent claim 27 does not specify the feature wherein magnetic fields are applied from at least two directions to the container unit with said container unit situated between the fields.

Consequently, it would be easy for a person skilled in the art to conceive of configuring the invention pertaining to the introduction of biological material presented in document 1, so that the form of the particles is modified into a known form, such as that disclosed in document 2, in order to improve the introduction rate of the particles.

Claims 28-30

The invention set forth in claims 28-30 lacks novelty and does not involve an inventive step in the light of document 2 cited in the international search report.

Document 2 discloses magnetic particles used in the introduction of biological material into cells and indicates that it is preferable for the shape of said magnetic particles to be non-spherical and to have corners

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and for them to be a needle shape preferable with a rod-shaped cross section. Needle-shaped magnetic particles are usually considered to be magnetized in a longitudinal direction and to be easily magnetizable.